IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
WESTERN DIVISION

WILLIE WASHINGTON, ***individually,***
and on behalf of all others similarly situated,

Plaintiff,

v.

Case No. 5:11CV42-DCB-RHW

XANODYNE PHARMACEUTICALS, INC., and
ELI LILLY AND COMPANY,

Defendants.

BRIEF IN SUPPORT OF DEFENDANT ELI LILLY AND COMPANY'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM PURSUANT TO FED. R. CIV. P. 12(B)(6)

PRELIMINARY STATEMENT

Pursuant to FED. R. CIV. P. 12(b)(6), Defendant, Eli Lilly and Company ("Lilly"), moves to dismiss the claims asserted by Plaintiff Willie Washington, individually, and on behalf of all others similarly situated ("Plaintiff") stemming from his alleged ingestion of a propoxyphene product on or about September 10, 2009, to October 11, 2010. Specifically, Plaintiff alleges that, as a result of taking "Xanodyne's Darvocet®", Plaintiff suffered from a heart attack on October 13, 2010. (Compl. ¶¶ 9-10). Lilly divested its entire line of propoxyphene medications in the United States, including Darvocet and Darvon®, in February 2002, and, as such, cannot possibly be liable for Plaintiff's alleged September, 2009 to October, 2010 ingestion and October, 2010 alleged injury.

Plaintiff filed this product liability action on March 16, 2011, asserting six causes of action arising from alleged injuries as a result of Plaintiff's alleged use of Darvocet. (Compl.). Plaintiff asserts that from September 10, 2009, to October 11, 2010, he "took Xanodyne's

Darvocet as directed by physicians." (Compl. ¶ 9). Plaintiff asserts that on October 13, 2010, he suffered from a heart attack and that "Plaintiff's heart attack was caused or significantly contributed to by his ingestion of Darvocet." (Compl. ¶ 12).

Plaintiff has alleged identical claims, set forth in six counts against two defendants: Lilly, and Xanodyne Pharmaceuticals, Inc. ("Xanodyne"). Plaintiff alleges that "Xanodyne is the current holder of the New Drug [Application] (NDA) for Darvocet, the rights for which it purchased from AAIPharma Services in 2005." (Compl. ¶ 14). Throughout the Complaint, Plaintiff lumps together Lilly and Xanodyne as "Defendants" and collectively levies legal conclusions without factual support for the elements of his claims. (*See generally* Compl.).

Plaintiff admits in the Complaint that Xanodyne was the holder of the NDA at the time of Plaintiff's alleged ingestion of Darvocet. (Compl. ¶ 14). Additionally, Lilly could not, under any possible scenario, have been responsible for Plaintiff's injuries because Lilly, ***in 2002***, ***divested*** Darvon (propoxyphene) and Darvocet (propoxyphene with acetaminophen) to an unrelated company (not a defendant to this action), which thereafter sold the product lines to Xanodyne in 2005. As set forth more fully below, Lilly's divestiture of Darvocet occurred over ***seven years*** before Plaintiff's alleged ***2009*** ingestion of Darvocet - a fact which is both confirmed as a matter of law by judicially noticeable, public, U.S. Government records (*see infra*) and admitted by the Plaintiff himself. *See* Compl. ¶ 14 (alleging that Xanodyne is the current holder of the approved NDA for Darvocet).

As set forth below, federal law mandates that the Food and Drug Administration ("FDA") publish on a monthly basis the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS – commonly known as the "Orange Book" – to identify which pharmaceutical company is authorized to distribute which prescription medications in the United States. The

Orange Book makes clear that Lilly was not authorized by the FDA to market or distribute Darvon or Darvocet in 2009 at the time of Plaintiff's alleged ingestion of the product. Records from the United States Patent and Trademark Office ("USPTO") further demonstrate that Lilly divested these products seven years before the use of the product by the Plaintiff, as the trademark registrations for Darvon and Darvocet were assigned from Lilly to aaiPharma in 2002. (*See infra.*)

Because judicially-noticeable facts – as well as Plaintiff's own allegations – establish that he cannot state a viable claim against Lilly, and because he has failed to satisfy the basic pleading requirements of FED. R. CIV. P. 8, Lilly respectfully asks the Court to grant its motion and dismiss Plaintiff's claims against it in their entirety pursuant to FED. R. CIV. P. 12(b)(6).

NATURE OF THE PROCEEDINGS

Plaintiff, Willie Washington, alleges that from September 10, 2009, to October 11, 2010, he "took Xanodyne's Darvocet as directed by his physicians." (Compl. ¶ 9). Plaintiff alleges that on October 13, 2010, he suffered from a heart attack and that prior to this alleged heart attack, he had never been diagnosed with any heart condition. (Compl. ¶¶ 10-11). Additionally, Plaintiff alleges that his alleged heart attack "was caused or significantly contributed to by his ingestion of Darvocet." (Compl. ¶ 12). As a result, Plaintiff has brought six causes of action against Lilly and Xanodyne. (Compl.)

Plaintiff admits that Xanodyne was the holder of the NDA. (Compl. ¶ 14). As mentioned above and discussed in more detail below, Lilly divested Darvocet over seven years before Plaintiff's alleged ingestion.[1] Despite this divestiture, Plaintiff argues, among other things, that "Defendants" failed to adequately test, failed to adequately warn, defectively

[1] Plaintiff's lack of specific allegations against Lilly and allegations of having "received Defendant Xanodyne's product" and "took Xanodyne's Darvocet" seems to indicate that Plaintiff was fully aware of Lilly's divestiture. (Compl. ¶¶ 8-9).

designed Darvocet, breached warranties, and misrepresented the specific product allegedly administered to Plaintiff. (Compl.) However, as set forth below, Lilly did not market, promote, or sell Darvocet in 2009 or 2010. In fact, judicially noticeable U.S. Government records make clear that Lilly divested the product in 2002 in the United States and was no longer authorized by the FDA to market, sell, or distribute Darvocet long before Plaintiff was prescribed the medication in 2009. Because Plaintiff fails to make any specific allegations against Lilly, he admits that Xanodyne was the NDA holder, and Plaintiff's alleged ingestion of the product, in 2009 and 2010 (Compl. ¶¶ 9, 14), did not take place until seven years after Lilly divested the product, Plaintiff's Complaint confirms that Lilly could not have sold, distributed, or had regulatory responsibility for the product that forms the basis of his suit.

Nevertheless, Plaintiff's Complaint asserts six causes of action against Lilly.[2] (Compl. ¶¶ 29-63). However, Plaintiff fails to allege facts sufficient to support the most basic element of his product liability claims - that the Plaintiff was injured as a result of a product sold and distributed by Lilly. In fact, there are direct, publicly available facts to the contrary. Thus, Plaintiff has failed to state a facially plausible claim for relief. Plaintiff's Complaint fails to satisfy the basic pleading requirements of Rule 8 of the Federal Rules of Civil Procedure. Consequently, Lilly's motion to dismiss should be granted with prejudice and Plaintiff's claims against Lilly should be dismissed in their entirety without leave to amend.

[2] The counts include: Negligent Failure to Test, Negligent Failure to Warn, Strict Liability, Breach of Warranty, Misrepresentation, and Punitive Damages.

ARGUMENT

I. THE COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED AGAINST LILLY

A. Legal Standard

FED. R. CIV. P. 12(b)(6) permits a court to dismiss a claim when the plaintiff "fail[s] to state a claim upon which relief can be granted." Motions to dismiss test the legal sufficiency of a complaint. *Essex Ins. Co. v. Greenville Convalescent Home, Inc.*, 4:05-cv-103, 2006 WL 2347520, at *1 (N.D. Miss. Aug. 11, 2006). While the Court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff, *Sonnier v. State Farm Mut. Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007), it need not accept sweeping legal conclusions cast in the form of factual allegations, unwarranted inferences, or unsupported conclusions. *Plotkin v. IP Axess, Inc.*, 407 F.3d 690, 696 (5th Cir. 2005); *R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005). More specifically, a "complaint must contain sufficient factual matter, accepted as true to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that ***the defendant*** is liable for the misconduct alleged." *Ashcroft v. Iqbal*, --- U.S. ----, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (emphasis added)). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]' 'that the pleader is entitled to relief.'" *Iqbal*, 129 S. Ct. at 1950 (quoting FED. R. CIV. P. 8(a)(2)).

Rule 8(a) requires that the complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief" or be subject to dismissal. FED. R. CIV. P. 8(a)(2). Accordingly, to comply with Rule 8, the complaint must provide "more than labels and

conclusions" or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. Moreover, "[t]he pleading must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." *Id.* This is because, as the Supreme Court has explained, "[w]ithout some factual allegation in the complaint, it is hard to see how a claimant could satisfy the requirement of providing not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests." *Id.* at 555 n.3. Accordingly, courts "are not bound to accept as true a legal conclusion couched as a factual allegation" and pleadings that lack a "statement of circumstances, occurrences, and events in support of the claim presented" should be dismissed. *Id; see also Iqbal*, 129 S. Ct. at 1950 (applying *Twombly* and noting that Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions."). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555. *See also Cuvillier v. Taylor,* 503 F.3d 397, 401 (5th Cir. 2007), *citing Twombly*, 550 U.S. at 558 ("when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court.") (internal quotation marks omitted).

B. Judicially-Noticeable Facts Confirm that Lilly Did Not Market, Sell, or Distribute Darvocet In the United States During the Relevant Time.

In evaluating a Rule 12(b)(6) motion, this Court may consider the allegations in the Complaint, matters of public record, and matters of which a court may take judicial notice. *See Davis v. Biloxi Public Sch. Dist.*, No. 1:10cv172-LG-RHW, 2011 WL 198124, at *2 (S.D. Miss. Jan. 20, 2011), *citing Hall v. Hodgkins*, 305 Fed. Appx. 224, 227 (5th Cir. 2008); 5A C.A. Wright & A.R. Miller, *Federal Practice & Procedure*, § 1357, at 299 (1990). This Court is authorized to take judicial notice of historical facts, dates and other indisputable facts that are

easily verifiable by authoritative sources. *See* FED. R. EVID. 201(b). The Court may also rely upon documents added to the record as part of this motion to dismiss, *i.e.*, supporting memorandum and affidavits, to the extent Plaintiff had notice of the documents and relied upon them in framing the Complaint in this action. *See Cortec Indus. Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991).

In the present case, government records and filings, readily available to the general public, make clear that Lilly could not have marketed, sold or distributed the product, Darvocet, that Plaintiff alleges caused his injuries. Specifically, judicially noticeable, public, U.S. Government records conclusively establish that, as of the date of Plaintiff's alleged ingestion, which allegedly began in September, 2009 to October, 2010, Lilly did not market, distribute, or have the rights to Darvocet, but rather that Lilly divested the product seven years before in 2002. It is a fundamental principle of product liability law that the defendant had to actually have sold and distributed the product that caused a plaintiff's injury. Otherwise, the plaintiff will be unable to establish causation, an element essential to the plaintiff's case on which the plaintiff will bear the burden of proof at trial. Here, Plaintiff fails to, and cannot, allege this essential element as to Lilly. Accordingly, the Complaint "fail[s] to state a claim upon which relief can be granted," and this Court should grant Lilly's motion to dismiss pursuant to FED. R. CIV. P. 12(b)(6).

1. The FDA Orange Book

Under federal law, no one may market or distribute a drug for which it is not authorized. 21 U.S.C. § 355(a). Federal law mandates that the FDA publish the Orange Book to identify which pharmaceutical companies are authorized to distribute a particular prescription medication in the United States. 21 U.S.C. § 355(j)(7)(A)(ii); *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08 Civ. 03710, 2010 WL 3447906, at *2 (S.D.N.Y. Sept. 2, 2010) (explaining that after the FDA approves the NDA, the NDA and its related patents are listed in the "Approved Drug Products

with Therapeutic Equivalence Evaluations publication, also known as the 'Orange Book.'"); *Wyeth v. Sun Pharms. Indus. Ltd.*, No. 09-11726, 2010 WL 746394, at *1 (E.D. Mich. Mar. 2, 2010) (stating that the FDA is required to maintain and update the Orange Book to keep medical professionals and the public apprised of the approved products, including generic products). The information maintained in the Orange Book is based on the FDA's own records and research. 21 U.S.C. § 355(j)(7)(A); 45 Fed. Reg. 72582 ("[a]ll drug products on the List have been fully reviewed and approved for safety and effectiveness by the FDA"); 45 Fed. Reg. 72585 ("[i]n the absence of an official List, pharmacists . . . would be required to make their own evaluations of therapeutic equivalence, usually without the comprehensive information available to the agency").

As a result, the Orange Book, including the truth of its contents, qualifies for judicial notice as a public record under Rule 201 of the Federal Rules of Evidence. *See* FED. R. EVID. 201(b) (stating that a judicially noticeable fact is one that is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned"); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (finding that the district court took appropriate judicial notice of publicly available documents produced by the FDA); *Timmons v. Linvatec Corp.*, 263 F.R.D. 582, 585 (C.D. Cal. 2010) (taking judicial notice of the Orange Book and holding that "judicially-noticeable facts demonstrate that [the pharmaceutical company] did not manufacture or sell [the product] during the relevant time period"); *Combs v. Stryker Corp.*, No. 2:09-cv-02018, 2009 WL 4929110, at *2 (E.D. Cal. Dec. 14, 2009) (same); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of the FDA's Center for Drug Evaluation and Research Listing of New Generic Drug Approvals - "Orange Book"); *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008)

(stating that a court "may take judicial notice of and consider the public records of the FDA . . . without transforming this motion into a motion for summary judgment"); *Phillips v. Stryker Corp.*, No. 3:09-cv-488, 2010 WL 2270683, at *5 (E.D. Tenn. June 3, 2010) (taking judicial notice of FDA public documents).

Accordingly, Lilly submits for the Court's review as Exhibit A to the Motion to Dismiss excerpts from the 30th Edition (2010) Orange Book and the 31st Edition (2011) Orange Book,[3] which conclusively establish that Lilly did not market, sell or distribute Darvocet (or Darvon) during the relevant time. (*See* Exh. A-1 to Motion, Excerpts from the 2010 Orange Book, Product Name Sorted by Applicant List, at p. B-21-22; and Exh. A-2 to Motion, Excerpts from the 2011 Orange Book, Product Name Sorted by Applicant List, at p. B-74 (listing all approved Lilly products).) Instead, Darvocet and Darvon were sold in the United States, until withdrawal from the market in November 2010, exclusively by entities other than Lilly, including Xanodyne. *See* Exh. A-3 to Motion, Excerpts from 2010 Orange Book, Prescription Drug Product List, at pp. 3-7, 3-325, 3-326, 6-5, 6-6, 6-31, 6-32, 6-33, 6-268 and Exh. A-4 to Motion, Excerpts from 2011 Orange Book, Prescription Drug Product List, at pp. 3-7, 3-338, 6-6, 6-32, 6-33, 6-273, 6-274 (demonstrating that Lilly was not authorized to market and distribute Darvocet or Darvon in 2009 and 2010).

2. USPTO Records

Records maintained by the USPTO further demonstrate that Lilly divested Darvocet well before the alleged ingestion, as the trademark registration for Darvocet was assigned to aaiPharma on February 2, 2002. (*See* Exh. B to Motion, USPTO, Trademark Assignment Abstract of Title, Darvocet; *see also* Exh. C to Motion, Trademark Assignment Abstract of Title,

[3] The 2010 Orange Book is current from January 1, 2009, to December 31, 2009. The 2011 Orange Book is current from January 1, 2010, to December 31, 2010.

Darvon.) The court may take judicial notice of these records from the USPTO website. *See United States v. Eagleboy*, 200 F.3d 1137, 1140 (8th Cir. 1999) (district court may take judicial notice of agency documents); *Kos Pharms. Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (taking judicial notice of the mark registration on the USPTO's website); *Super-Krete Intern., Inc. v. Sadleir*, 712 F. Supp. 2d 1023, 1029 n.1 (C.D. Cal. 2010) (same).

C. Plaintiff's Allegations Against Lilly Fail to Satisfy Rule 8 Because Lilly Did Not Sell or Distribute Darvocet In the United States During the Relevant Time Period.

The product allegedly ingested by Plaintiff in 2009 and 2010 was not sold or distributed by Lilly as evidenced by the judicially noticeable records. Without the requisite showing of causation, namely that a Lilly product caused his injuries, Plaintiff's claims fail as a matter of law.

"[I]t is incumbent upon the plaintiff in any products liability action to show that the defendant's product was the cause of the plaintiff's injuries." *Moore v. Mississippi Valley Gas Co.*, 863 So. 2d 43, 46 (Miss. 2003). *See also Sanchez v. Liggett & Myers, Inc.*, 187 F.3d 486, 491 (5th Cir. 1999) (stating that plaintiffs could prove causation only for the sellers of cigarettes decedent actually smoked). Mississippi law[4] requires that a plaintiff establish that the product was the proximate cause of the plaintiff's injuries. *3M Co. v. Johnson*, 895 So. 2d 151, 161 (Miss. 2005). "Proximate cause" is defined as the 'cause which in natural and continuous sequence unbroken by any efficient intervening cause produces the injury and without which the result would not have occurred.'" *Forbes v. Gen. Motors Corp.*, 935 So. 2d 869, 880 (Miss. 2006) (citations omitted).

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[4] In this diversity action, Mississippi substantive law determines Plaintiff's right to recovery. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

In fact, Mississippi's Product Liability Act specifically compels Plaintiff to identify the product alleged to have caused his injury as one manufactured by Lilly. *See* MISS. CODE ANN. § 11-1-63(a)(iii) (stating that Plaintiff must establish that "[a] defective and unreasonable condition of the product proximately caused the damages for which recovery is sought."); *Dufour v. Agco Corp.*, No. 1:05cv169-WJG-JMR, 2009 U.S. Dist. LEXIS 4954, at *3-4 (S.D. Miss. Jan. 22, 2009) (Mississippi's product liability statute requires that plaintiffs establish product identification). *See also Monsanto Co. v. Hall*, 912 So. 2d 134, 137 (Miss. 2005) (stating that plaintiffs' claims failed when they could not establish product identification in an asbestos case).

In addition to the judicially noticeable U.S. Government records detailed above, Plaintiff fails to make *any* allegations against Lilly and admits on the face of his Complaint that Xanodyne held the NDA. (Compl. ¶ 14). Plaintiff states that he was prescribed Darvocet in September, 2009. (Compl. ¶ 7). However, Xanodyne, not Lilly, held the NDA. (Compl. ¶ 14). Lilly divested Darvocet in 2002.

In a nearly identical case, *In re Minnesota Breast Implant Litig.*, the court held that 3M could not be held liable for any claims after it divested the product to another company. *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 872 (D. Minn. 1998). In addressing plaintiffs' many claims, the court noted that 3M could not be held liable when it did not manufacture the products plaintiffs received and, thus, could not have owed plaintiffs any duty. *Id.* at 872-73. More specifically, the court rejected plaintiffs' arguments that 3M was liable for negligent design noting that once 3M sold the business, it no longer had any control over the design. *Id.* at 873. Plaintiffs also argued that 3M was liable for failure to warn and breach of warranty. *Id.* at 874-75. The court dismissed these claims noting that 3M was not the seller and had no duty to warn. *Id.* Plaintiffs further claimed that 3M was liable for negligence per se for

violations of the Food, Drug and Cosmetic Act. *Id.* at 875. Again, the court noted that 3M could not "be said to have had the power to prevent any alleged violations of the Food, Drug, and Cosmetic Act." *Id.* Finally, the court dismissed the fraud claims noting that there was no relationship between 3M and the plaintiffs; additionally, 3M, at the time it was the manufacturer, could not have foreseen that plaintiffs would be using the product. *Id.* In sum, the court dismissed all claims against 3M as it had divested the product line and did not distribute the product received by plaintiffs. *Id.*

Similarly, it is clear that Plaintiff cannot establish that Lilly, which divested the product in 2002, is responsible for Plaintiff's alleged injuries. As such, all claims must also be dismissed because Lilly divested Darvocet *seven* years prior to Plaintiff's alleged ingestion. Thus, Lilly cannot, under established Mississippi law, be held liable for a product sold by another manufacturer. Judicially noticeable records establish that Lilly no longer marketed, sold, distributed or promoted Darvocet in the United States at the time of the Plaintiff's alleged ingestion and alleged injuries. Thus, the necessary proximate causation for Plaintiff's claims are lacking and cannot be established. Similar to the court's finding in *In re Breast Implant Litig.*, Lilly cannot be held liable for injuries occurring after divestiture. Simply put, because Lilly did not sell, distribute or promote Darvocet, the product alleged to be at issue in this matter, it is not legally or factually responsible for Plaintiff's injuries and Plaintiff's Complaint fails to state a claim upon which relief can be granted against Lilly.

D. The Complaint Fails to Satisfy Rule 8 Because It Fails to Differentiate Among the Defendants.

Irrespective of the fact that Plaintiff cannot state a claim against Lilly due to Lilly's divestiture of the product seven years before the instant claims arose, Plaintiff has failed to separate his allegations amongst the Defendants. When two or more defendants are named,

plaintiffs must "differentiate their allegations" to give proper notice as to the allegations applicable to each defendant. *Swartz v. KPMG LLP*, 476 F.3d 756, 764-65 (9th Cir. 2007). Failure to separate the allegations as to each defendant justifies dismissal. *Pietrangelo v. NUI Corp.*, No. Civ. 04-3223, 2005 WL 1703200, at *10 (D.N.J. July 20, 2005) ("the [c]omplaint fails to satisfy even the liberal notice pleading standard of Rule 8(a) because [p]laintiff fails to differentiate between the defendants. Here, Plaintiff's complaint instead lumps all of the defendants together and accuses every defendant of breaching all of the asserted fiduciary duties"). *See also Ill. Cent. R.R. v. Adams*, 922 So. 2d 787, 790 (Miss. 2006) (stating that "the complaint must disclose, in general terms, what **each defendant** did wrong to each plaintiff, and when and where the alleged wrong took place.") (emphasis added);[5] *Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir. 2001) (affirming dismissal because the complaint "lump[ed] all the defendants together in each claim and provid[ed] no factual basis to distinguish their conduct"); *Classen v. Immunotherapies, Inc. v. Biogen IDEC*, 381 F. Supp. 2d 452, 455 (D. Md. 2005) (dismissing complaint that "fail[ed] to delineate the particular acts of infringement attributable to each Defendant"); *Asad v. Providian Bank, N.A.*, 234 Fed. Appx. 511, 511-12 (9th Cir. 2007) (unpublished) (affirming dismissal of complaint that failed to "specify which claims were set forth against which defendants").

Moreover, *Twombly* requires that the "[f]actual allegations must be enough to raise a right to relief above the speculative level." 550 U.S. at 555. Thus, in addressing a motion to dismiss, courts should consider whether the factual allegations in the complaint are facially plausible. As the Supreme Court elaborated in *Ashcroft v. Iqbal*, the facial plausibility requires plaintiffs to plead ***specific*** facts implicating each named defendant:

> A claim has facial plausibility when the plaintiff pleads factual

[5] FED. R. CIV. P. 8 is substantially similar to MISS. R. CIV. P. 8.

> content that allows the court to draw the reasonable inference that ***the defendant*** is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

129 S. Ct. at 1949 (citations omitted; emphasis added).

Here, Plaintiff alleges that "Defendants" are liable for the six alleged counts. Plaintiff's broad and sweeping allegations are set forth without any factual specificity and carelessly asserted against all "Defendants" throughout the entire Complaint. For example, in paragraph 45 of the Complaint, Plaintiff generically asserts that "[a]s a result of Defendants' marketing and promotion of said defective and unreasonably dangerous drug, Plaintiff ingested Darvocet and has suffered injury, loss, and damages as aforesaid." (Compl. ¶ 45). These allegations fail to identify which Defendant is allegedly responsible for the conclusory conduct of which Plaintiff complains. Even where Plaintiff attempts to link Defendants to the proximate cause standard, the allegations are just as conclusory. *See, e.g.,* Compl. ¶ 45 (alleging that "[a]s a result of Defendants' marketing and promotion of said defective and unreasonably dangerous drug, Plaintiff ingested Darvocet and has suffered injury, loss, and damages as aforesaid").

Accordingly, Plaintiff's Complaint neither provides proper notice to Lilly of the claims against it nor allows the Court to draw the reasonable inference that Lilly is liable for the misconduct alleged and thus Lilly should be dismissed. *Iqbal*, 129 S. Ct. at 1954 ("Rule 8 does not empower [Plaintiff] to plead the bare elements of [her] cause of action, affix the label 'general allegation,' and expect his complaint to survive a motion to dismiss."). *See McConnell v. Funk*, No. 2:10-cv-97KS, 2010 WL 4736257, at *3 (S.D. Miss. Nov. 16, 2010) (dismissing plaintiff's claims which did "not contain any specific allegations against [the defendant] nor [did] the

Complaint contain any factual support for any allegation that [the defendant] was in any way . . . responsible for the subject incident.").

Conclusory and generic allegations have been found to be insufficient under Rule 8 by multiple other district courts in the context of pharmaceutical litigation. For example, in *Dittman*, the plaintiff alleged that he was injured by the implantation of "a pain pump loaded with anesthetic agents" into his shoulder. *Dittman v. DJO, LLC,* No. 08-CV-02791-WDM-KLM, 2009 WL 3246128, at *1 (D. Colo. Oct. 5, 2009). In his complaint, however, the plaintiff failed to "identify which specific medication was allegedly used during his procedure . . . ." *Id.* Thus, in addition to finding the plaintiff's claims to be time barred, the court determined that the plaintiff had not sufficiently alleged that any of the named defendants' products were actually used in his pain pump. *Id.* at *3 ("Plaintiff has no facts, only speculation, on which to base his claim that defendants' products caused or contributed to his injury."). Because of this "fatal" deficiency, the court dismissed the complaint, holding that the "mere possibility . . . that the medicine used could have been made by these defendants, rather than by any number of other manufacturers of anesthesia drugs, is not adequate to state a claim under the prevailing standards as set forth by *Twombly* and *Iqbal*." *Id.* The court dismissed the plaintiff's claims against AstraZeneca and another anesthetic manufacturer with prejudice without leave to amend. *Id.*

In *Sherman*, the complaint contained "generalized descriptions" – *i.e.*, "anesthetics," "anesthetic drugs," and "pain relief drugs" – of the anesthetic administered, and the plaintiff "conspicuously fail[ed]" to allege that AstraZeneca was responsible for the pain medication at issue. *Sherman v. Stryker Corp.*, No. SACV 09-224 JVS, 2009 WL 2241664, at *4-5 (C.D. Cal. Mar. 30, 2009). Based upon the plaintiff's vague allegations, the court dismissed the complaint with prejudice as to AstraZeneca and another anesthetic manufacturer, holding that there were

"not even enough facts for a reasonable inference of liability," since the complaint alleged several different types or brands of medication that *might* have been used and contained no allegation that AstraZeneca was responsible for the medication *actually* used. *Id.* at *5.[6]

In Plaintiff's Complaint, the allegations against Lilly are even more egregious than the complaints in *Dittman* and *Sherman*. In *Dittman* and *Sherman*, the complaints wholly failed to identify the product that caused the plaintiffs' injuries or which named defendant, if any, was the seller of that product. In this case, Plaintiff actually alleges that he "received Defendant Xanodyne's product" and "took Xanodyne's Darvocet." (Compl. ¶¶ 8-9). Additionally, Plaintiff alleges that Xanodyne, not Lilly, held the NDA at the time of Plaintiff's alleged ingestion, *seven years* after Lilly divested the product. In essence, Plaintiff freely admits that the product received by him could not have been sold or distributed by Lilly. Thus, Lilly cannot possibly be liable when it had divested Darvocet and Plaintiff could not possibly have received a product marketed or distributed by Lilly.[7] Accordingly, Plaintiff's claims against Lilly should be dismissed in their entirety.

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[6] *See also Daughtery v. I-Flow, Inc. et al.*, No. 3:09-cv-2120-P, 2010 WL 2034835, at *3 (N.D. Tex. April 29, 2010) (granting defendants' motions to dismiss because "[plaintiff] has not set forth allegations sufficient or specific enough to plead the existence of a causal connection between his injury and the conduct of any particular defendant(s)."); *Peterson v. Breg, Inc., et al.*, No. 2:09-cv-2044-JWS, 2010 WL 2044248, at *2 (D. Ariz. April 29, 2010) (same); *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSx), 2010 WL 1339948, at *3 (C.D. Cal. March 30, 2010) (granting defendants' motions to dismiss for each plaintiff's failure to allege the identity of the particular defendant responsible for the specific product administered to him); *Haskins v. Zimmer Holdings Inc., et al.*, No. 1:09-cv-236, 2010 WL 342552, at *5 (D. Vt. Jan. 29, 2010) (granting defendant's motion to dismiss and stating that "Plaintiffs must at least allege in their complaint that [the defendant's] product was administered to [plaintiff] . . . This threshold allegation is necessary to show a plausible entitlement to relief); *Gilmore v. DJO, Inc.*, 663 F. Supp. 2d 856, 862 (D. Ariz. 2009) (granting defendant's motion to dismiss because the plaintiffs had "done little more than allege that [the defendants] caused them harm" and "that is not sufficient to withstand a motion to dismiss").

[7] Plaintiff has filed this action individually, and on behalf of others similarly situated. The claims of the class representative, Willie Washington, against Lilly should be dismissed for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6). As such, once Mr. Washington's claims against Lilly are dismissed, there will be no class representative and class justification should be denied. *Murray v. Fidelity Nat'l Fin., Inc.*, 594 F.3d 419, 421 (5th Cir. 2010) ("a purported class action becomes moot when the personal claims are satisfied and no class has been certified.")

II. PLAINTIFF HAS FAILED TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED FOR FRAUDULENT MISREPRESENTATION.

To the extent Plaintiff claims fraudulent misrepresentation, Plaintiff's claim is deficient and fails to state a claim upon which relief can be granted. Plaintiff fails to set forth specific allegations against Lilly, and therefore, his fraud claims must be dismissed in their entirety.

Plaintiff's claims for fraud against "Defendants" are set forth in paragraphs 52-58. Plaintiff makes the blanket allegation that Lilly gave the impression that Darvocet was safe and effective and "Plaintiff's physicians relied on . . . the decades of uncorrected marketing by Lilly, in prescribing Darvocet to Plaintiff." (Compl. ¶¶ 53, 57).

FED. R. CIV. P. 9(b) requires that a party alleging fraud must state with particularity, the circumstances constituting fraud. The Fifth Circuit has noted that a plaintiff must "plead enough facts to illustrate 'the who, what, when, where, and how' of the alleged fraud." Additionally, "[i]n cases concerning fraudulent misrepresentation and omission of facts, Rule 9(b) typically requires the claimant to plead the type of facts omitted, the place in which the omissions should have appeared, and the way in which the omitted facts made the representations misleading." *United States v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 381 (5th Cir. 2004) (*citing* 2 James W. Moore, MOORE'S FEDERAL PRACTICE § 9.03[1][b] at 9-18, 9-19 (3d ed. 2003)). *See also Peters v. Metro. Life Ins.*, 164 F. Supp. 2d 830, 834 (S.D. Miss. 2001) (stating that a fraud claim must state all the elements and the allegations must be factual, not conclusory); *Allen v. Tyson Foods Inc.*, 153 F. Supp. 2d 886, 889-890 (S.D. Miss. 2001) (at a minimum, the complaint must allege the time, place, and contents of the representations).

Plaintiff's fraud claim is insufficiently pled. Notably absent from the Plaintiff's Complaint are any of the particulars required for pleading fraudulent misrepresentation. Namely, Plaintiff fails to even identify the persons making the alleged misstatements or when or where

the statements occurred. (*See* Compl. ¶¶ 52-58). Indeed, it is not surprising that Plaintiff fails to meet the requirements of Federal Rule 9 where the broad, sweeping claims are set forth generically in terms of "Defendants" rather than specifically against an individual defendant. The allegations as pled amount to little more than conclusory statements, unsupported by fact, that are entirely void of the requisite "particularity [of] the circumstances constituting fraud." FED. R. CIV. P. 9(b). In sum, there simply are no factual allegations in the pleadings to support a misrepresentation claim against Lilly and dismissal of the count in the Complaint, to the extent it alleges fraudulent misrepresentation, is entirely proper.

III. PLAINTIFF IS NOT ENTITLED TO DISCOVERY OR PERMITTED LEAVE TO AMEND.

This Court should dismiss the claims against Lilly without further discovery and without leave to amend. The Federal Rules of Civil Procedure mandate an "inquiry reasonable under the circumstances" into the evidentiary support for all factual contentions prior to filing a pleading. FED. R. CIV. P. 11(b). In this case, Plaintiff has alleged that from September, 2009 to October, 2010 he ingested Darvocet, and, thereafter, on October 13, 2010, Plaintiff alleges he suffered from a heart attack. (Compl. ¶¶ 9-10). As demonstrated above, Lilly could not have been the correct Defendant when it divested the product seven years before the alleged injury. As such, any amendment would be futile. *See Young v. Scruggs*, No. 1:09-cv-669KS, 2010 WL 2301641, at *10 (S.D. Miss. June 7, 2010) ("Most certainly, the rules pertaining to amending a complaint do not require courts to indulge in useless gestures.") (citation omitted); *Pan Islamic Trade Corp. v. Exxon Corp.*, 632 F.2d 539, 546 (5th Cir. 1980), *abrogated on other grounds* (noting that if a complaint as amended is still subject to dismissal, amendment should not be granted).

To be sure, any request for discovery to alter the allegations contained in Plaintiff's Complaint would run directly afoul of controlling United States Supreme Court precedent. In

Twombly and *Iqbal*, the Supreme Court made clear that a plaintiff who fails to meet the pleadings requirements of Rule 8(a)(2) at the outset should not be allowed to proceed to the discovery phase of the case in the hope that discovery might provide the evidence needed to support a claim against the defendant. *See Twombly*, 550 U.S. at 559 ("[i]t is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through 'careful case management' . . ."); *Iqbal*, 129 S. Ct. at 1954-55 ("[b]ecause [plaintiff's] complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise"). Plaintiff has no basis for suing Lilly because Lilly divested the product in 2002, and as such, Lilly should not be subjected to costly discovery obligations. *See Ferrer v. Chevron Corp.*, 484 F.3d 776, 782 (5th Cir. 2007) (stating that plaintiffs are not entitled to discovery on a motion to dismiss because "a 12(b)(6) inquiry focus on the allegations in the pleadings, not whether a plaintiff actually has sufficient evidence to succeed on the merits.").

In this case, the Court should exercise its broad discretion to dismiss the claims against Lilly without leave to amend. Plaintiff does not make any specific allegations against Lilly, yet, Plaintiff still named Lilly as a Defendant. Lilly divested the product seven years before Plaintiff's alleged ingestion. This type of blatant disregard for the facts should not be rewarded by allowing Plaintiff to amend the Complaint or to blindly engage in a fishing expedition to pursue discovery against Lilly. Accordingly, Lilly requests that the Court grant its motion to dismiss, with prejudice.

CONCLUSION

For the reasons set forth above, Plaintiff's claims against Lilly do not meet the pleading requirements under the plain language of the Federal Rules of Civil Procedure. Accordingly, Lilly respectfully requests that the Court grant its motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FED. R. CIV. P. 12(b)(6).

This, the 5th day of May, 2011.

ELI LILLY AND COMPANY

/s/ Douglas J. Gunn
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CERTIFICATE OF SERVICE

I hereby certify that on May 5, 2011, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent a copy of the same upon the following:

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